

State of Arizona
House of Representatives
Fifty-first Legislature
Second Regular Session
2014

HOUSE CONCURRENT RESOLUTION 2005

A CONCURRENT RESOLUTION

ENACTING AND ORDERING THE SUBMISSION TO THE PEOPLE OF A MEASURE RELATING TO
THE USE OF INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS AND DEVICES.

(TEXT OF BILL BEGINS ON NEXT PAGE)

1 Be it resolved by the House of Representatives of the State of Arizona, the
2 Senate concurring:

3 1. Under the power of the referendum, as vested in the legislature,
4 the following measure, relating to the use of investigational drugs,
5 biological products or devices, is enacted to become valid as a law if
6 approved by the voters and on proclamation of the Governor:

7 AN ACT

8 AMENDING TITLE 36, ARIZONA REVISED STATUTES, BY ADDING CHAPTER
9 11.1; RELATING TO THE USE OF INVESTIGATIONAL DRUGS, BIOLOGICAL
10 PRODUCTS OR DEVICES.

11 Be it enacted by the Legislature of the State of Arizona:

12 Section 1. Title 36, Arizona Revised Statutes, is amended
13 by adding chapter 11.1, to read:

14 CHAPTER 11.1

15 TERMINAL PATIENTS' RIGHT TO TRY ACT

16 ARTICLE 1. GENERAL PROVISIONS

17 36-1311. Definitions

18 IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

19 1. "ELIGIBLE PATIENT" MEANS A PERSON TO WHOM ALL OF THE
20 FOLLOWING APPLY:

21 (a) THE PERSON HAS A TERMINAL ILLNESS AS DETERMINED BY
22 THE PERSON'S PHYSICIAN AND A CONSULTING PHYSICIAN.

23 (b) THE PERSON'S PHYSICIAN HAS DETERMINED THAT THE PERSON
24 HAS NO COMPARABLE OR SATISFACTORY UNITED STATES FOOD AND DRUG
25 ADMINISTRATION APPROVED TREATMENT OPTIONS AVAILABLE TO DIAGNOSE,
26 MONITOR OR TREAT THE DISEASE OR CONDITION INVOLVED AND THAT THE
27 PROBABLE RISK TO THE PERSON FROM THE INVESTIGATIONAL DRUG,
28 BIOLOGICAL PRODUCT OR DEVICE IS NOT GREATER THAN THE PROBABLE
29 RISK FROM THE DISEASE OR CONDITION.

30 (c) THE PERSON HAS RECEIVED A PRESCRIPTION OR
31 RECOMMENDATION FROM THE PERSON'S PHYSICIAN FOR AN
32 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

33 (d) THE PERSON HAS GIVEN WRITTEN INFORMED CONSENT FOR THE
34 USE OF THE INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE
35 OR, IF THE PATIENT IS A MINOR OR LACKS THE MENTAL CAPACITY TO
36 PROVIDE INFORMED CONSENT, A PARENT OR LEGAL GUARDIAN HAS GIVEN
37 WRITTEN INFORMED CONSENT ON THE PATIENT'S BEHALF.

38 (e) THE PERSON HAS DOCUMENTATION FROM THE PERSON'S
39 PHYSICIAN THAT THE PERSON HAS MET THE REQUIREMENTS OF THIS
40 PARAGRAPH.

41 2. "INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE"
42 MEANS A DRUG, BIOLOGICAL PRODUCT OR DEVICE THAT HAS SUCCESSFULLY
43 COMPLETED PHASE ONE OF A CLINICAL TRIAL, BUT HAS NOT BEEN
44 APPROVED FOR GENERAL USE BY THE UNITED STATES FOOD AND DRUG

1 ADMINISTRATION AND REMAINS UNDER INVESTIGATION IN A CLINICAL
2 TRIAL.

3 3. "PHYSICIAN" MEANS THE PHYSICIAN WHO IS PROVIDING
4 MEDICAL CARE OR TREATMENT TO THE ELIGIBLE PATIENT FOR THE
5 TERMINAL ILLNESS BUT DOES NOT INCLUDE A PRIMARY CARE PHYSICIAN.

6 4. "TERMINAL ILLNESS" MEANS A DISEASE THAT, WITHOUT
7 LIFE-SUSTAINING PROCEDURES, WILL RESULT IN DEATH IN THE NEAR
8 FUTURE OR A STATE OF PERMANENT UNCONSCIOUSNESS FROM WHICH
9 RECOVERY IS UNLIKELY.

10 36-1312. Availability of investigational drugs,
11 biological products or devices; costs;
12 insurance coverage

13 A. A MANUFACTURER OF AN INVESTIGATIONAL DRUG, BIOLOGICAL
14 PRODUCT OR DEVICE MAY MAKE AVAILABLE THE MANUFACTURER'S
15 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE TO ELIGIBLE
16 PATIENTS PURSUANT TO THIS ARTICLE. THIS ARTICLE DOES NOT
17 REQUIRE THAT A MANUFACTURER MAKE AVAILABLE AN INVESTIGATIONAL
18 DRUG, BIOLOGICAL PRODUCT OR DEVICE TO AN ELIGIBLE PATIENT.

19 B. A MANUFACTURER MAY:

20 1. PROVIDE AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR
21 DEVICE TO AN ELIGIBLE PATIENT WITHOUT RECEIVING COMPENSATION.

22 2. REQUIRE AN ELIGIBLE PATIENT TO PAY THE COSTS OF OR
23 ASSOCIATED WITH THE MANUFACTURE OF THE INVESTIGATIONAL DRUG,
24 BIOLOGICAL PRODUCT OR DEVICE.

25 3. REQUIRE AN ELIGIBLE PATIENT TO PARTICIPATE IN DATA
26 COLLECTION RELATING TO THE USE OF THE INVESTIGATIONAL DRUG,
27 BIOLOGICAL PRODUCT OR DEVICE.

28 C. THIS ARTICLE DOES NOT REQUIRE A HEALTH CARE INSURER OR
29 ANY STATE AGENCY TO PROVIDE COVERAGE FOR THE COST OF ANY
30 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE. A HEALTH
31 CARE INSURER MAY PROVIDE COVERAGE FOR AN INVESTIGATIONAL DRUG,
32 BIOLOGICAL PRODUCT OR DEVICE.

33 36-1313. Action against physician license or health care
34 institution license; prohibition

35 A. NOTWITHSTANDING ANY OTHER LAW, A STATE REGULATORY
36 BOARD MAY NOT REVOKE, FAIL TO RENEW OR TAKE ANY OTHER ACTION
37 AGAINST A PHYSICIAN'S LICENSE ISSUED PURSUANT TO TITLE 32,
38 CHAPTER 13 OR 17 BASED SOLELY ON A PHYSICIAN'S RECOMMENDATION TO
39 AN ELIGIBLE PATIENT REGARDING OR PRESCRIPTION FOR OR TREATMENT
40 WITH AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

41 B. NOTWITHSTANDING ANY OTHER LAW, A STATE AGENCY MAY NOT
42 TAKE ANY ACTION AGAINST A HEALTH CARE INSTITUTION'S LICENSE
43 BASED SOLELY ON THE INSTITUTION'S PARTICIPATION IN THE TREATMENT
44 OR USE OF AN INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE
45 UNDER THIS CHAPTER.

1 36-1314. Violation: classification
2 AN OFFICIAL, EMPLOYEE OR AGENT OF THIS STATE WHO BLOCKS OR
3 ATTEMPTS TO BLOCK ACCESS OF AN ELIGIBLE PATIENT TO AN
4 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE IS GUILTY OF
5 A CLASS 1 MISDEMEANOR.

6 Sec. 2. Findings: intent

7 A. The legislature finds and declares that:

8 1. The process of approval for investigational drugs,
9 biological products and devices in the United States often takes
10 many years.

11 2. Patients who have a terminal illness do not have the
12 luxury of waiting until an investigational drug, biological
13 product or device receives final approval from the United States
14 food and drug administration.

15 3. The standards of the United States food and drug
16 administration for the use of investigational drugs, biological
17 products and devices may deny the benefits of potentially
18 life-saving treatments to terminally ill patients.

19 4. Patients who have a terminal illness have a
20 fundamental right to attempt to pursue the preservation of their
21 own lives by accessing available investigational drugs,
22 biological products and devices.

23 5. The use of available investigational drugs, biological
24 products and devices is a decision that should be made by the
25 patient with a terminal illness in consultation with the
26 patient's physician and is not a decision to be made by the
27 government.

28 B. It is the intent of the legislature that allowing for
29 the terminal patients' right to try act to apply to patients
30 with nonterminal illnesses furthers the purpose of this act.

31 Sec. 3. Severability

32 If a provision of this act or its application to any
33 person or circumstance is held invalid, the invalidity does not
34 affect other provisions or applications of the act that can be
35 given effect without the invalid provision or application, and
36 to this end the provisions of this act are severable.

37 2. The Secretary of State shall submit this proposition to the voters
38 at the next general election as provided by article IV, part 1, section 1,
39 Constitution of Arizona.